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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,348	03/14/2007	Andrew Peter Worsley	P08804US00/RFH	6403

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1623	

MAIL DATE	DELIVERY MODE
11/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,348	WORSLEY, ANDREW PETER	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/14/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 16-23 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "particularly endogeneous depression," renders the claims indefinite. More specifically it is unclear whether or not applicant's method treats only endogeneous depression or is specific for treating endogeneous depression or also treats other forms of depression.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 8, 10 and 11 of U.S. Patent No. 6,335,323 B2 (Worsley). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Patent No. 6,335,323 B2 are drawn to a pharmaceutical composition containing as the only pharmaceutical active components vitamin B_{12}, and a precursor or inducer of a neurotransmitter selected from the group consisting of L-phenylalanine, L-tyrosine, tryptophan and tyramine. The claims of the instant application are drawn to a pharmaceutical composition for treatment of depression having a combination of pharmaceutically active components consisting only of or including any one of a combinations set which includes the pharmaceutically active components vitamin B_{12}, and the precursor or inducer of a neurotransmitter, L-phenylalanine, L-tyrosine, tryptophan and tyramine. Thus, the instant claim 23 is seen to be anticipated by the claims 7, 8, 10 and 11 of U.S. Patent No. 6,335,323 B2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Loder et al. (US 6,096,737).

In claim 23, applicant claims a pharmaceutical composition for treatment of depression having a combination of pharmaceutically active components consisting only of or including any one of the combinations set out in claim 16. Loder et al. disclose applicant's composition comprising a combination of lofepramine and L-phenylalanine (see col. 2, lines 44-67; see also abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., to treat depresion, does not further limit claims drawn to a composition or product. See, e.g., Ex parte Marsham, 2 USPQ2d 1647 (1987) and In re Hack 114, USPQ 161.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Worsley et al. (US 6,335,323 B2).

In claim 23, applicant claims a pharmaceutical composition for treatment of depression having a combination of pharmaceutically active components consisting only of or including any one of the combinations set out in claim 16. Worsley et al. disclose applicant's composition having a combination of pharmaceutically active components comprising a combinations set out in claim 16 (see claims 7, 8, 10 and 11; see also abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., to treat depresion, does not further limit claims drawn to a composition or product. See, e.g., Ex parte Marsham, 2 USPQ2d 1647 (1987) and In re Hack 114, USPQ 161.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunes et al. (WO 98/09623).

In claim 16, applicant claims a method of treatment of a patient suffering from a form of depression, particularly endogenous depression, comprising administering to the patient any one of the following combinations of components:

I. A, B and C or C' II. A and B III. B and C or C' IV. A and C or C'

wherein A is an antidepressant, B is vitamin B12, and C is a precursor or inducer of a neurotransmitter (other than L-tryptophan), C' is L-tryptophan, said components being administered simultaneously or separately, in amounts which in combination have the effect of ameliorating the depression. Claims 17-19, 21 and 22 are drawn to said method wherein the depression is specific, wherein the antidepressant is specific and includes lofepramine, wherein C is L-phenylalanine, L-tyrosine or tyramine and wherein the combination of components is L-tryptophan and a SSRI. Claim 20 is drawn to said method wherein B (vitamin B12) is in the form of cyanocobalamin or hydroxycobalamin.

Brunes et al. suggest that patients with depression can receive depression therapy with antidepressants, particularly lofepramine and optionally with the addition of neurotransmitter precursors such as L-phenylalanine, L-tyrosine, L-DOPA and tryptophan (see claims 5 and 4). Furthermore, Brunes et al. disclose that vitamin B12 can be used together with antidepressants and neurotransmitter precursors (see page 2, 3rd paragraph).

The difference between applicant's claimed method and the method suggested by Brunes et al. is that Brunes et al. do not exemplify the said method, per se. However, Brunes et al. suggest that patients with depression can receive depression therapy with antidepressants, particularly lofepramine and optionally with the addition of neurotransmitter precursors such as L-phenylalanine, L-tyrosine, L-DOPA and tryptophan (see claims 5 and 4).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have treated depression in a patient by administering to said patient a combination of antidepressants, such as lofepramine and a neurotransmitter precursors such as L-phenylalanine, L-tyrosine, or tryptophan as suggested by Brunes et al., based on factors such as the type and severity of the depression and the type, age and weight of the patient treated.

One having ordinary skill in the art would have been motivated, to treat depression in a patient by administering to said patient a combination of antidepressants, such as lofepramine and a neurotransmitter precursors such as L-phenylalanine, L-tyrosine, or tryptophan as suggested by Brunes et al., based on factors such as the type and severity of the depression and the type, age and weight of the patient treated.

In claim 23, applicant claims a pharmaceutical composition for treatment of depression having a combination of pharmaceutically active components consisting only of or including any one of the combinations set out in claim 16.

Brunes et al. suggest that lofepramine and neurotransmitter precursors such as L-phenylalanine, L-tyrosine, L-DOPA and tryptophan (see claims 5 and 4) can be used or administered to treat depression in a patient. Furthermore, Brunes et al. disclose that vitamin B12 can be used together with antidepressants patients with depression can receive depression

therapy with antidepressants, particularly and neurotransmitter precursors (see page 2, 3rd paragraph). It should be noted that it is well settled that "intended use" of a composition or product, e.g., to treat depresion, does not further limit claims drawn to a composition or product. See, e.g., Ex parte Marsham, 2 USPQ2d 1647 (1987) and In re Hack 114, USPQ 161.

The difference between applicant's claimed composition and the composition suggested by Brunes et al. is that Brunes et al. do not exemplify the said composition, per se. However, Brunes et al. suggest said composition can be used to treat depression in a patient.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared a composition comprising a combination of antidepressants, such as lofepramine and a neurotransmitter precursors such as L-phenylalanine, L-tyrosine, or tryptophan as suggested by Brunes et al., to treat depression in a patient, based on factors such as the type and severity of the depression and the type, age and weight of the patient treated.

One having ordinary skill in the art would have been motivated, to prepare a composition comprising a combination of antidepressants, such as lofepramine and a neurotransmitter precursors such as L-phenylalanine, L-tyrosine, or tryptophan as suggested by Brunes et al., to treat depression in a patient, based on factors such as the type and severity of the depression and the type, age and weight of the patient treated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the

examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

11/5/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

November 2, 2007.